

REMARKS

Claims 1, 3-5, 7-10, 12-18, 20, and 23-31 are pending. Applicants have cancelled claim 6 without prejudice or disclaimer and reserve the right to pursue the cancelled subject matter in the future. Applicants amended claims 23-26 to update the claim dependencies based on the cancellation of claim 6 and to replace the word "or" with "and" for purposes of clarity. Claim 16 has been amended to replace the term "talk" with the correct term "talc" as shown on page 8, line 15 of the specification. No new matter has been added into the claims.

Interview Summary

Applicants thank Examiner Tran for meeting to discuss this application with their representative James Balls on April 27, 2010, at the United States Patent & Trademark Office.

Applicants' representative expressed applicants' desire to work with the examiner to bring this case to a successful conclusion, as the application has been in prosecution for more than eight years (since early 2003). The examiner indicated she would re-consider the prior art in view of applicants' positions and recommend claim amendments (if further amendments are considered necessary) to place the application in condition for allowance. The points raised by applicants during the interview are provided below in response to the rejections set forth in the Office Action dated December 15, 2009.

Response to Rejection Under 35 U.S.C. § 102(b)

Claims 1, 3-10, 13, 16-17, 20, 23-27, and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lundberg *et al.* (WO 96/24338).

The rejection is improper because the dosage forms of Lundberg *et al.* have an enteric coating and a separating layer, both of which are excluded by the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Lundberg *et al.* describes coating an alkaline core material with an enteric coating and forming a separating layer between the core and the enteric coating *in situ*. See, e.g., Lundberg *et al.*, column 5, lines 51-58.

During the interview of April 29, 2010, the examiner explained that Lundberg *et al.* might anticipate the claims if the “enteric coating” of Lundberg *et al.* is identical to the semipermeable membrane of the instant claims. In other words, if the “enteric coating” of Lundberg *et al.* and the “semipermeable membrane” of the instant claims are made-up of the same materials it is of no consequence that they are called different names.

In response to the Examiner’s concerns, Applicants’ representative pointed out that even if the “enteric coating” of Lundberg *et al.* were somehow interpreted to be the semipermeable membrane according to the instant claims, the dosage forms of Lundberg *et al.* still cannot anticipate the claims because they include a separating layer formed *in situ* (the instant claims exclude a separating layer). Accordingly, the rejection is improper and should be withdrawn.

Response to Rejection Under 35 U.S.C. § 103(a)

Claims 1, 3, 6-8, 12-18, 20 and 25-29 were rejected under 35 U.S.C. § 103(a) as being obvious over Nara *et al.* (US 6,245,351) in view of Bergstrand *et al.* (US 5,753,265), Lundberg *et al.* (US 6,013,281), Hodges *et al.* (US 5,225,202), and Zetner (US 4,795,644).

The rejection is improper because:

1. The references do not account for every element of the claims; and
2. The references teach away from proceeding as applicants have done.

The references do not account for every element of claims because they do not describe a core material, without a separating layer, coated with a semipermeable membrane comprising a single polymer composition. To establish *prima facie* obviousness, all the claim limitations must be taken into account. The Board of Patent Appeals and Interferences recently stated:

When determining whether a claim is obvious, an examiner must make a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art. Thus, obviousness requires a suggestion of all limitations in a claim. Moreover, as the Supreme Court recently stated, “*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness.

In re Wada and Murphy, Appeal 2007-3733 (Bd. Pat. App. & Inter. 2008) (emphasis in original, internal citation omitted).

As pointed out in applicants’ March 7, 2008 response, Nara *et al.*, the primary reference relied upon in the rejection, describes a core material coated with a polymer composition containing two or three polymers, *i.e.*, a water insoluble polymer, a swellable polymer, and an optional hydrophilic substance (which includes certain polymers). *See* column 6, lines 16-21, claims 1 and 9, and Examples 1-11. Nara *et al.* also describes a separating layer in column 6, lines 1-10.

In the section entitled “Response to Arguments” on page 10 of the Office Action, it states that applicants’ claims do not exclude a separating layer comprising a single polymer composition. *See* Office Action dated December 15, 2010, page 10, lines 13-16. It is not clear to applicants how the examiner is construing the claims to include a separating layer even though the claims explicitly recite that “the core material is not coated with a separating layer.”

Because the references do not account for a core material coated with a semipermeable membrane comprising a single polymer composition without a separating layer, the rejection is improper and should be withdrawn.

The rejection is further improper because the references actually teach away from coating a core material with a semipermeable membrane comprising a single polymer composition without a separating layer. Where a reference teaches away from and discourages a person skilled in the art from doing what is claimed, the reference establish “the very antithesis of obviousness.” *In re Buehler* 185 USPQ 781 (CCPA 1975).

All of the references cited against the claims teach that omeprazole should be coated with an enteric coating (or a composition comprising multiple polymers) and should include a separating layer. The prior art must be considered in its entirety, including disclosures that teach away from the claims. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983); *see also* MPEP 2145.

Nara *et al.* is the primary reference of the rejection. It lists examples of drugs that may be employed in a controlled-release composition in column 3, lines 34-64, reproduced below.

Examples of the drug for the present invention include, but are not limited to, opioid compounds such as morphine or pharmacologically acceptable salts thereof (e.g., hydrochloride, sulfate), hydromorphone, oxycodone, methadone, meperidine, dihydrocodeine, codeine, dihydromorphone, buprenorphine and fentanyl; antiinflammatory agents such as Naplozen Na, isopropylantipyryne HCl, ibuprofen, ketoprofen, diclofenac Na; sympathomimetics such as ephedrine HCl, salbutamol sulfate, terbutaline sulfate and phenylpropanolamine HCl; anti-allergic drugs such as phenylamine and terfenadine; antihistamines such as chlorpheniramine maleate, diphenhydramine HCl and clemastine fumarate; cardiac drugs such as procainamide hydrochloride, propranolol hydrochloride and quinidine sulfate; antihypertensive drugs such as metoprolol, captopril, hydralazin HCl and diltiazem HCl; antibiotics such as Penicillin V Potassium, Cloxacillin Na, Metronidazole hydrochloride, amoxicillin, cephalexin and clarithromycin; bronchodilators such as theophylline and salbutamol; anti-arrhythmic drugs such as procainamide and quinidine; antineoplastics such as flutamide and fluorouracil; anticonvulsants such as phenytoine Na, ethosuximide and valproate Na; central nervous-acting substances such as chlorpromazine hydrochloride, diazepam and perphenazine; gastrointestinal agents such as ranitidine HCl, cimetidine famotidine, **omeprazole** and lansoprazole; antidiabetic agents such as acarbose voglibose and tolbutamide; cholinergic agent such as bethanechol chloride, neostigmine bromide and carbachol; vitamins; amino acids; and peptides (emphasis added).

Omeprazole is one of many alternative compounds in this enormous list of diverse drug substances. Moreover, omeprazole is not exemplified in any examples or otherwise indicated as preferred (it is mentioned only once). Nara *et al.* repeatedly exemplifies morphine hydrochloride

and phenylpropanolamine hydrochloride, not omeprazole. A prior art reference that teaches or suggests a preferred embodiment different from the claimed subject matter weighs against a determination of obviousness. *In re Baird*, 16 F.3d 380, 82-83, (Fed. Cir. 1994); *see also* MPEP 2144.08(II)(A)(4).

Assuming one would select omeprazole from the enormous list in Nara *et al.* (even though Nara *et al.* does not exemplify or otherwise indicate that omeprazole is preferred), the reference teaches that the core material should be coated with a composition comprising multiple polymers. *See, e.g.*, the abstract and the examples. Nara *et al.* describes a core material coated with a composition comprising a water insoluble polymer, a swellable polymer, and an optional hydrophilic substance (which can be a polymer). Additionally, Nara *et al.* teaches the use of a protective layer. *See* column 6, lines 1-10 and 16-21, claims 1 and 9, and Examples 1-11. Thus, Nara *et al.* specifically teaches away from proceeding as applicants have done by requiring the use of a coating comprising multiple polymers and by encouraging the use of a protective layer.

The Office Action cites Bergstrand *et al.* (US 5,753,265) as applicable to claims 9-10 and 30-31. Bergstrand *et al.* explains that H⁺K⁺-ATPase inhibitors such as omeprazole “are best protected from contact with acidic gastric juice by an enteric coating layer.” *See* column 4, lines 5-7 (emphasis added). It goes on to describe a separating layer in column 7, lines 43-50. Thus, Bergstrand *et al.* teaches away from proceeding as applicants have done by indicating the need for an enteric coating and a separating layer.

The Office Action cites Lundberg *et al.* (US 6,013,281) as applicable to claims 9-10. Lundberg *et al.* is directed to an enteric coated pharmaceutical dosage form of omeprazole. *See, e.g.*, claim 3 and example 2. It also describes a separating layer. *See, e.g.*, the abstract. Thus, Lundberg *et al.* teaches away from proceeding as applicants have done by indicating the need for an enteric coating and a separating layer.

The Office Action cites Hodges *et al.* (US 5,225,202) as applicable to claims 30-31. Hodges *et al.* is directed to an enteric coated pharmaceutical composition for a medicament that is sensitive to a low pH environment. *See* the abstract. It describes using a “subcoat layer” to act

as a physical barrier between the core and outer enteric coating layer in column 4, lines 59-65. Thus, Hodges *et al.* teaches away from proceeding as applicants have done by indicating the need for an enteric coating and a separating layer.

The art of record explicitly teaches the need to coat omeprazole with a composition comprising multiple polymers and/or an enteric coating. The art of record also explicitly teaches the need for a separating layer. In the instant case, applicants proceeded contrary to the teachings of the art and developed a dosage form that does not include an enteric coating or a separating layer.

In sum, the rejection is improper and should be withdrawn because the references do not account for every element of the claims and because the art teaches away from proceeding as applicants have done.

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees to Deposit Account No. 22-0185.

A petition for a two-month extension of time is being submitted with this response. Applicants believe no additional fees are due at this time. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 15652-00020-US from which the undersigned is authorized to draw.

Dated: May 17, 2010

Respectfully submitted,

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